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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER WORLEY, CATHY KINGDON	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/519,811	Applicant(s) ERICKSON ET AL.	
	Examiner Cathy K. Worley	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
 4a) Of the above claim(s) 1-5, 14-21, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-13, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/28/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/28/04; 3/15/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction/Election

1. In response to the communication received on May 14, 2007 from Mark T. Skoog, the election with traverse of group VI, claims 7 (in part), 6, 8-13, 22, 25, and 26, is acknowledged. The Applicant traverses on the grounds that it would not be unduly burdensome for the Examiner to search and examine all the claims. This is not persuasive, because the claims are directed to different inventions that would require separate sequence searches, and this causes an undue burden. Furthermore, the restriction requirement was based on PCT rules for lack of unity, therefore, there is no need to establish a search burden to justify the restriction. The restriction requirement is deemed to be proper and is MADE FINAL.

Specification

2. The specification is objected to because the Brief Description of the Drawings does not include a description of panels A-D for figure 11. Because figure 11 has four separate panels labeled A, B, C, and D; the description of the drawing must include a description for each of the panels.

3. The specification is objected to because it contains an embedded hyperlink and/or other forms of browser-executable code. On page 27 in the second paragraph there is an embedded link. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP 608.01.

4. The disclosure is objected to because of the following informalities: on page 26 in line 3, there is a nonsense symbol that looks like a box; this needs to be deleted. Appropriate correction is requested.

Claim Objections

5. Claims 6, 7, 22, 25, and 26 are objected to because of the following informalities:

A) Claim 6 is directed to a regulatory element "obtained" by the method of claim 4, however, claim 4 only provides method steps for identifying an element; it does not provide any steps for "obtaining" a regulatory element.

B) Claim 7 continues to recite non-elected subject matter. The Applicant elected the invention directed to SEQ ID NO:4, therefore, parts "ii" and "iii" of claim 7 should be deleted.

C) Claim 22 is missing a hyphen between "harvest" and "inducible".

D) Claims 25 and 26 recite a Markush group of different plant species. In order to be a proper Markush list, the list should not include the article "or", but it

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should include the article "and" between the last two items on the list; ie. "sudan grass, and sorghum".

Appropriate correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 6 is rejected because the claimed invention is directed to non-statutory subject matter.

This claim reads on a molecule per se which is found in nature and thus, is unpatentable to Applicants. DNA that occurs in nature in a wild-type plant comprises harvest-inducible regulatory elements, therefore claim 6, as written, encompasses a naturally occurring molecule, and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that the recitation - - An isolated - - be inserted in place of "A".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6-13, 25, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any harvest-inducible regulatory element and to a harvest-inducible regulatory element selected from the group consisting of SEQ ID NO:4, a complement thereof, a fragment thereof, a complement of the fragment, a nucleic acid that hybridizes to SEQ ID NO:4, a nucleic acid that hybridizes to a fragment or the complement of the fragment. The claims are also drawn to a construct, vector, and a plant or plant part comprising said regulatory element.

The Applicants describe the H7 promoter of SEQ ID NO:4 (see page 35, Table 2) and they describe it to be 634 bp in length (see sequence listing). They describe a

construct comprising the H7 promoter fused to the GUS coding sequence (see third paragraph on page 33).

The Applicants do not describe any fragments or complementary sequences of SEQ ID NO:4 that retain harvest-inducible regulatory activity. Further the specification does not describe any DNA molecules that hybridize under stringent conditions to SEQ ID NO:4 that retain the harvest-inducible regulatory activity of the intact promoter of SEQ ID NO:4.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The Applicants fail to describe a representative number of regulatory elements with harvest-inducible regulatory activity that comprise a nucleotide sequence consisting of a complement or fragment or complement of a fragment of SEQ ID NO:4 or a nucleic acid that hybridizes to SEQ ID NO:4. The Applicants only describe the nucleic acid of SEQ ID NO:4. Furthermore, the Applicants fail to describe structural features common to members of the claimed genus of regulatory

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elements. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for harvest-inducible regulatory activity, it remains unclear what features identify elements capable of such activity. Since the genus of regulatory elements has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Nucleic acids that consist of a complement or fragment or complement of a fragment of SEQ ID NO:4 or a nucleic acid that hybridizes to SEQ ID NO:4 encompass a large number of molecules, many of which would not comprise harvest-inducible regulatory activity, and most of which were not in the possession of the Applicant at the time of filing. The Applicants have reduced to practice only one regulatory element (the promoter of SEQ ID NO:4) in an experiment that demonstrates harvest-inducible promoter activity. Accordingly, the specification fails to provide an adequate written description to support the genus of nucleic acids with harvest-inducible regulatory activity that consists of a complement or fragment or complement of a fragment of SEQ ID NO:4 or a nucleic acid that hybridizes to SEQ ID NO:4 as set forth in the claims. (See Written Description guidelines published in the Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices: p. 1099-1111).

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8. Claims 6-13, 25, and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a harvest-inducible regulatory element comprising SEQ ID NO:4 or a fragment thereof wherein said fragment comprises harvest-inducible regulatory activity, does not reasonably provide enablement for regulatory elements consisting of a complement of SEQ ID NO:4 or a complement of a fragment of SEQ ID NO:4 or a nucleic acid that hybridizes to SEQ ID NO:4 or its complement. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to any harvest-inducible regulatory element and to a harvest-inducible regulatory element selected from the group consisting of SEQ ID NO:4, a complement thereof, a fragment thereof, a complement of the

fragment, a nucleic acid that hybridizes to SEQ ID NO:4, a nucleic acid that hybridizes to a fragment or the complement of the fragment. The claims are also drawn to a construct, vector, and a plant or plant part comprising said regulatory element.

The nature of the invention is a harvest-inducible promoter from alfalfa.

The Applicants teach the H7 promoter of SEQ ID NO:4 (see page 35, Table 2) and they disclose it to be 634 bp in length (see sequence listing). They teach a construct comprising the H7 promoter fused to the GUS coding sequence (see third paragraph on page 33).

The Applicants do not teach any fragments or complementary sequences of SEQ ID NO:4 that retain harvest-inducible regulatory activity. Further the specification does not teach any DNA molecules that hybridize under stringent conditions to SEQ ID NO:4 that retain the harvest-inducible regulatory activity of the intact promoter of SEQ ID NO:4.

Nucleic acids that hybridize to SEQ ID NO:4 can have numerous additions, insertions, deletions or substitutions relative to SEQ ID NO:4 and still retain the ability to hybridize. The state-of-the-art is such that one of skill in the art cannot predict which additions, deletions, substitutions, or insertions within a full-length promoter can be tolerated such that the promoter retains its activity. Mutation of promoter sequences produces unpredictable results. Donald et al (1990, EMBO J. 9:1717-1726) in a mutational analysis of the *Arabidopsis rbcS-1A* promoter found

that the effect of a particular mutation was dependent on promoter fragment length (paragraph spanning pg 1723-1724). The region of a given promoter that has a specific activity cannot be predicted and involves the complex interaction of different subdomains (Benfrey et al, 1990, Science 250:959-966, see Abstract, Fig. 3-5). Even a very small region may be critical for activity, and the criticality of a particular region must be determined empirically (Kim et al, 1994, Plant Mol. Biol. 24:105-117, Tables 1-4, Abstract, Fig. 1-2).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of skill in the art to make multitudes of molecules encompassing complements and sequences that hybridize to SEQ ID NO:4 and test each one for seed-specific promoter activity.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to make and use the claimed invention, and therefore, the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 6-13, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cramer et al US Patent No.5,670,349, issued on Sept. 23, 1997.

The claims are drawn to a harvest-inducible regulatory element and constructs, vectors, plants, and plant parts comprising said element.

Cramer et al teach a harvest-inducible gene (see Figure 15 and Table 3) and the promoter (also referred to as regulatory element) from this gene (see column 37). The method by which the harvest-inducible regulatory element of the instant claim 6 is obtained does not distinguish it over the prior art regulatory element taught by Cramer et al, therefore the teaching of Cramer et al anticipate the instant claim 6.

The promoter taught by Cramer et al inherently comprises the ability to hybridize to SEQ ID NO:4 under some stringency conditions, therefore, because no particular hybridization conditions are required in the instant claims, the promoter taught by Cramer et al is encompassed by the instant claim 7.

Cramer et al teach a construct comprising said promoter (see claim 1), a plant and plant tissues comprising said construct (see claim 1), they teach a plasmid "pSJL330.1" which is a vector comprising said regulatory element (see column 37, lines 10-21), they teach tomatoes transformed with this construct (see column 37, lines 35-37).

Allowable Subject Matter

10. Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. The prior art does not teach or fairly suggest the nucleic acid sequence of SEQ ID NO: 4.

11. No claim is allowed.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW


ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER